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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,153	10/09/2006	Suzana Rosic-Kablar	14096.0056USWO	3182

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MERCHANT & GOULD PC
P.O. BOX 2903
MINNEAPOLIS, MN 55402-0903

EXAMINER	
HILL, KEVIN KAI	
ART UNIT	PAPER NUMBER
1633	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/551,153	ROSIC-KABLAR ET AL.	
	Examiner	Art Unit	
	KEVIN K. HILL	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-38* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Election/Restrictions

1. **Restriction is required under 35 U.S.C. 121 and 372.**

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, Applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-6, 28 and 36, drawn to undifferentiated canine embryonic stem cells.

Group II, claim(s) 7-8, drawn to cells differentiated *in vitro* from canine embryonic stem cells.

Group III, claim(s) 10, drawn to genetically modified canine embryonic stem cells.

Group IV, claim(s) 12-15, drawn to a method for producing purified canine embryonic stem cells comprising (a) obtaining a canine embryo at a morula to blastocyst stage; (b) removing inner cell mass (ICM) cells from the canine embryo; (c) culturing inner cell mass (ICM) cells in the presence of a feeder layer and one or more proliferation agent to promote proliferation of undifferentiated stem cells; and (d) recovering stem cells.

Group V, claim(s) 16, drawn to a method for producing purified canine embryonic stem cells, the method further comprising the step of inducing differentiation of the embryonic stem cells into cells that exhibit morphological, physiological, functional, and/or immunological features of somatic and germ cells.

Group VI, claim(s) 19-21, drawn to a blastocyst to which has been introduced one or more canine embryonic stem cells and a chimeric non-human animal which is the progeny of said blastocyt.

Group VII, claim(s) 22-24, drawn to a method of making a chimeric non-human animal.

Group VIII, claim(s) 25-27 and 33-34, drawn to a method of using canine embryonic stem cells for the treatment of a condition, wherein the condition is hemophilia.

Group IX, claim(s) 25-27 and 33-34, drawn to a method of using canine embryonic stem cells for the treatment of a condition, wherein the condition is muscular dystrophy.

Group X, claim(s) 25-27 and 33-34, drawn to a method of using canine embryonic stem cells for the treatment of a condition, wherein the condition is MPS-1.

Group XI, claim(s) 25-27 and 33-34, drawn to a method of using canine embryonic stem cells for the treatment of a condition, wherein the condition is glycogen storage disease.
Group XII, claim(s) 25-27 and 33-34, drawn to a method of using canine embryonic stem cells for the treatment of a condition, wherein the condition is narcolepsy.
Group XIII, claim(s) 25-27 and 33-34, drawn to a method of using canine embryonic stem cells for the treatment of a condition, wherein the condition is thrombasthenia.
Group XIV, claim(s) 25-27 and 33-34, drawn to a method of using canine embryonic stem cells for the treatment of a condition, wherein the condition is Von Willebrand Disease.
Group XV, claim(s) 25-27 and 33-34, drawn to a method of using canine embryonic stem cells for the treatment of a condition, wherein the condition is osteogenesis.
Group XVI, claim(s) 25-27 and 33-34, drawn to a method of using canine embryonic stem cells for the treatment of a condition, wherein the condition is nephritis.
Group XVII, claim(s) 25-27 and 33-34, drawn to a method of using canine embryonic stem cells for the treatment of a condition, wherein the condition is retinal atrophy.
Group XVIII, claim(s) 25-27 and 33-34, drawn to a method of using canine embryonic stem cells for the treatment of a condition, wherein the condition is severe combined immunodeficiency disease.
Group XIX, claim(s) 25-27 and 33-34, drawn to a method of using canine embryonic stem cells for the treatment of a condition, wherein the condition is hematopoietic disorder.
Group XX, claim(s) 25-27 and 33-34, drawn to a method of using canine embryonic stem cells for the treatment of a condition, wherein the condition is autoimmune disorder.
Group XXI, claim(s) 25-27 and 33-34, drawn to a method of using canine embryonic stem cells for the treatment of a condition, wherein the condition is cancer.
Group XXII, claim(s) 25-27 and 33-34, drawn to a method of using canine embryonic stem cells for the treatment of a condition, wherein the condition is heart disease.
Group XXIII, claim(s) 25-27 and 33-34, drawn to a method of using canine embryonic stem cells for the treatment of a condition, wherein the condition is motor neuron disease.
Group XXIV, claim(s) 25-27 and 33-34, drawn to a method of using canine embryonic stem cells for the treatment of a condition, wherein the condition is degenerative bone and joint diseases.

Group XXV, claim(s) 25-27 and 33-34, drawn to a method of using canine embryonic stem cells for the treatment of a condition, wherein the condition is atherosclerosis.
Group XXVI, claim(s) 29-32, drawn to a method of screening drugs on canine embryonic stem cells.
Group XXVII, claim(s) 35, drawn to a business method using embryonic stem cells.
Group XXVIII, claim(s) 37-38, drawn to a primer that hybridizes to a canine OCT4 nucleotide sequence, wherein said primer comprises the sequence of SEQ ID NO:1 or 2.
Group XXIX, claim(s) 38, drawn to a primer that hybridizes to a canine POU5 nucleotide sequence, wherein said primer comprises the sequence of SEQ ID NO:5 or 6.

Claims 9 and 17-18 link Groups I-III.
Claim 11 links Groups IV-V.

2. The inventions listed as Groups I-XXIX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reasons:

A 371 case is considered to have unity of invention only when there is a technical relationship among those inventions involving one or more of the same or corresponding technical features. The expression "special technical feature' means those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. In the instant application, claims are drawn, in part, to undifferentiated canine embryonic stem cells, differentiated cells and tissues derived from undifferentiated canine embryonic stem cells, and to oligonucleotide primers that hybridize to canine Oct4 or canine POU5 nucleic acid sequences. Thus, *a priori*, the claims do not share the same or corresponding technical feature because those of ordinary skill in the art recognize that Oct4 is a different gene than POU5, and that oligonucleotide primers are distinctly different compositions than cells, and that undifferentiated embryonic stem cells are distinctly different cell compositions than differentiated cells and tissues. Furthermore, the International Searching Authority has already established that Lack of Unity exists for reasons of record.

Inventions I-III, VI and XXVIII-XXIX are directed to related products. The related inventions are distinct if: (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have materially different design, function and effect because those of ordinary skill in the art would recognize that undifferentiated embryonic stem cells possess distinctly different biological properties than differentiated cells, that genetic modification necessarily imparts a distinctly different special technical feature upon the cells, and that non-human animals possess a distinctly different phenotype [design, mode of operation, function and effect] than a cell line. Similarly, the POU5 and OCT4 primers are distinctly different from cellular compositions and non-human animals. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Inventions IV-V and VIII-XXVII are directed to related processes. The related inventions are distinct if: (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed are of materially different design to make distinctly different products or treat etiologically and pathologically distinct diseases, for example. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Inventions I-III and VI and Inventions IV-V and VII are related as processes of making and products made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the methods may be practiced to make different products, and the cell and organism products may be made by another and materially different process.

Inventions I-III and Inventions VIII-XXVII are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different

product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the processes may be practiced with a plurality of distinctly different cell compositions.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;

(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention**.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, Applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, Applicant must indicate which of these claims are readable upon the elected invention.

Should Applicant traverse on the ground that the inventions are not patentably distinct, Applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The Examiner has required restriction between product and process claims. Where Applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the Examiner before the patent issues. See MPEP § 804.01.

Claims 9 and 17-18 link Groups I-III. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), Claims 9 and 17-18.

Claim 11 links Groups IV-V. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), Claim 11.

Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim(s) including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to KEVIN K. HILL whose telephone number is (571)272-8036. The Examiner can normally be reached on Monday through Friday, between 9:00am-6:00pm EST.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Joseph T. Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kevin K. Hill, Ph.D./
Examiner, Art Unit 1633

/Q. JANICE LI, M.D./
Primary Examiner, Art Unit 1633